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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Monica JÖNSSON et al.

FILING DATE

October 5, 2001

ATTORNEY'S DKT NO.

APPLICATION NO.

09/970,649

APPLICANT

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M	Artursson et al., "Characterization of Polyacryl Starch Microparticles as Carriers for Proteins and Disput Journal of Pharmaceutical Sciences, Vol. 73, No. 11, pp. 1507-1513, (1984)						
	Franssen et al., "A Novel Preparation Method for Polymeric Microparticles Without the Use of Organic Solvents," International Journal of Pharmaceutics, Vol. 168, pp. 1-7 (1998)						
	Fu et al., "Visual Evidence of Acidic Environment Within Degrading Poly(lactic-co-glycolic acid) (PLGA) Microspheres" Pharmaceutical Research, Vol. 17, No. 1, pp. 100-106 (2000)						
	Laakso et al., "Biodegradable Microspheres IV: Factors Affecting the Distribution and Degradation of Polyacryl Starch Microparticles," Journal of Pharmaceutical Sciences, Vol. 75, No. 10, pp. 962-967 (1986)						
	Laakso et al., "Biodegradable Microspheres X: Some Properties of Polyacryl Starch Microparticles Prepared from Acrylic Acid-Esterified Starch," <i>Journal of Pharmaceutical Sciences</i> , Vol. 76, No. 12, pp. 935-939 (1987)						
	Schröder, "Crystallized Carbohydrate Spheres as a Slow Release Matrix for Biologically Active Substances," Biomaterials, Vol. 5, pp. 100-104 (1984)						
	Schröder, "Crystallized Carbohydrate Spheres for Slow Release and Targeting," <i>Enzymology</i> , Vol. 112, No. 9, pp. 116-128 (1985)						
	Stenekes et al., "The Preparation of Dextran Microspheres in an All-Aqueous System: Effect of the Formulation Parameters on Particle Characteristics," <i>Pharmaceutical Research</i> , Vol. 15, No. 4 pp. 557-561 (1998)						
	Stjärnkvist <i>et al.</i> , "Biodegradable Microspheres XIII: Properties of the Crosslinking Chains in Polyacryl Starch Microparticles," <i>Journal of Pharmaceutical Sciences</i> , Vol. 78, No. 1, pp. 52-56 (1989)						
	Agersø et al., "Plasma Concentration of hGH and anti-hGH Antibodies After Subcutaneous Administration of hGH for 3 Weeks to Immunosuppressed Pigs," J. Pharmacol Toxicol No. 41 pp. 1-8 (1999)						
	Johnson et al., "A Month-Long effect From a Single Injection of Microencapsulated Human Growth Hormone," Nature Medicine, Vol. 2, No. 7 pp. 795-799 (1996)						
	Putney, "Encapsulation of Proteins for Improved Delivery," Current Opinion in <i>Chemical Biology</i> , Nol. 2, pp. 548-552 (1998)						
Gor	"Clean Package Insert," Nutropin Depot (somatropin(rDNA origin) for injectable suspension], Genentech, Inc., 1 DNA Way, South San Francisco, CA 940-4990, pp. 1-6 (December 13, 1999)						
Examiner (Signature ($\begin{array}{c c} \text{Date} & \text{S}/21/03 \\ \text{Considered} & \text{S}/21/03 \end{array}$						

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			LES. PATENT DOCUMENTS	Ö
	U.S. Patent D	NAME OF THE PROPERTY OF	<u> </u>	T
Examiner Initials	Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication (MM-DD-YYYY)
5H	5,981,719		Woiszwillo et al.	11/1999
	5,849,884		Woiszwillo et al.	12/1998
	5,776,885		Orsolini et al.	07/1998
	5,753,234		Lee et al.	05/1998
	5,667,808		Johnson <i>et al.</i>	09/1997
	5,654,010		Johnson <i>et al</i> .	08/1997
	5,622,657		Takeda <i>et al.</i>	04/1997
	5,578,709		Woiszwillo <i>et al.</i>	11/1996
	5,470,582		Supersaxo <i>et al.</i>	11/1995
	5,455,342		Redding, Jr.	10/1995
	5,407,609		Tice et al.	04/1995
	4,713,249		Schröder	12/1987
	4,389,330		Tice et al.	06/1983
	3,881,991		Kurimotor et al.	05/1975
	3,737,337		Schnoring et al.	06/1973
SH	3,691,090		Kitajima <i>et al.</i>	09/1972
			The state of the s	

FOREIGN PATENT DOCUMENTS

	Foreign Patent Document					
Examiner	Number	Kind Code		Date of Publication	Translation	
Initials		(if known)	Country	(MM-DD-YYYY)	Yes	no
481	WO 99/20253	A1	PCT	04/1999		I
	WO 99/00425	A1	PCT	01/1999		
	W0 97/14408	A1	PCT	04/1997		
	WO 96/10042	A1	PCT	04/1996		
	WO 94/12158	A1	PCT	06/1995		
	WO 93/21008	A1	PCT			
	EP 0 330 180	B2	EPO	03/1999		
	EP 0 688 429	B1	. EPO	02/1998		
	EP 0 540 582	B1	EPO	08/1994	T	
	EP 0 213 303	A2	EPO	03/1987		
4	WO 90/13780	A1	PCT	11/1990		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials

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